Exhibit 12

| | | | | 71.1.100.1.1 | | A THE WAY OF THE AMERICAN |
|------------|---------------|-------------------------------------|--------------------------------------|------------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Plaintiffs' | List of Custodia | ns for ZHP and Its Subsidiaries as of 12/5/2019 |
| First Name | Last name | Title | Department | Co. | Status | Explanation |
| | Т | T | I | I | T | Senior Management |
| | | | | | | |
| | | | | | | |
| | | E | | | | |
| | | Executive Vice President of ZHP, | | | | |
| | | CEO of Huahai | | | | |
| | | US, Prinston, | | | | |
| | | Solco, and PrinJohnson; Legal | | ZHP, Huahai | | Identified in Prinston's core document production more times than we can reference. Most senior manager involved in the day-to- day aspects of management for ZHP, Prinston, & Huahai US. Fully involved in valsartan contamination issues from initial |
| | | Representative of | | US, Prinston, | | reporting to FDA to present. Identified as a planned attendee in Prinston's 6.18.18 Email Meeting Request to FDA initially |
| _ | | Shaghai Syncores | | Solco, Syncores, | | advising the FDA of Valsartan's contamination (PRINSTON00000050). Led ZHP's investigation & response to the FDA's 483 |
| Jun | Du | and Prinbury | | and Prinbury | Disputed | observations made during the FDA inspection of Chuannan site 7.23.18 to 8.3.18 (PRINSTON0075644) |
| | | | | | | |
| | | Chairman and | | ZHP and | | He is the most senior officer in ZHP, and was the chairman of the board of directors. He was involved in a high level into the |
| Baohua | Chen | General Manager | | PrinJohnson | Disputed | valsartan contamination investigation. Jun Du reports directly to him. |
| | T | T | Analytical | An | alytical Depart | ment or "Analysis and Testing Center" |
| Min | Li | VP | Operations | ZHP | Agreed | |
| | | | | | | Org Chart; involved in testing tetrazole reaction in Valsartan, which is a crucual part of the manufacturing process resulting in |
| Jun | Wang | Finished Dose Gase Stage Team | Chuannan Branch Analytical Center | ZHP | Disputed | the contamination PRINSTON0074146. On 12/4/19, ZHP would not tell Plaintiffs the extent to which this person was involved in Valsartan. |
| | | - Suge reun | | | | |
| | Wang or | | | | | Is listed as a user on the chromatograms, which can detect nitrosamines, on the December 2013 solvent change submission to the |
| 0: | possibly just | | | ZIID | P - 10.8.19 | FDA PRINSTON00073055. As of 12/4/19, ZHP could not identify this person, despite the provision of the referenced |
| Qing | Wangqing | | | ZHP | r - 10.8.19 | document from Core Discovery. |
| | | Analytical and | | | | |
| | | Testing | | | | Org Chart. Also referenced in the text version of PRINSTON0076941, where he is designated as a member of the Quality |
| *** *** | | Department | Chuannan Branch | | D 44.00.40 | Control Team, which conducted the testing of Valsartan for impurities. As of 12/4/19, ZHP could not identify this person, |
| XiaXia | Kuang | Manager | Analytical Center | ZHP | P - 11.22.19 | despite the provision of the referenced document from Core Discovery and the person's presence on its organization chart. |
| | | | | | | |
| | | | | | | The org chart shows that this person had a significant role in ZHP's Analysis and Testing Department. ZHP has not provided |
| Class | V | Finished Dose | Chuannan Branch | ZIID | D 11 22 10 | Plaintiffs any additional information on this individual. On 12/4/19, ZHP refused to discuss the extent of this custodian's |
| Chun | Yang | Liquid Phase Team | Analytical Center | ZHP | P - 11.22.19 | involvement in Valsartan. |
| | | | | | | |
| | | | | | | |
| | | Raw Material Central Control | Chuannan Branch | | | The org chart shows that this person had a significant role in ZHP's Analysis and Testing Department. ZHP has not provided |
| Guang | Zheng | Instrument Team | Analytical Center | ZHP | P - 11.22.19 | Plaintiffs any additional information on this individual. |
| | | | | | | |
| | | | | | | |
| | | Raw Material | | | | |
| | | Central Control | Charana Barash | | | The second state of the se |
| XianLiang | Zhang | Physico-Chemical Team | Chuannan Branch Analytical Center | ZHP | P - 11.22.19 | The org chart shows that this person had a significant role in ZHP's Analysis and Testing Department. ZHP has not provided Plaintiffs any additional information on this individual. |
| | | | , , | | | Quality |
| Wei | Cheng | VP | API Quality Assurance | ZHP | Aomand | |
| WCI | Cheng | VF | Quality Assurance | ZHF | Agreed | |
| | | | (API Division- | | | |
| Jucai | Ge | Director | Chuannan Site) | ZHP | Agreed | |
| | | | Olite. | | | |
| | | | Quality Assurance Manager (API | | | |
| | | | Division- | | | |
| N 1: | | | Chuannan Site, | ZIID | l. , | |
| Yuelin | Hu | Assistant Director | East Zone) Corporate Quality | ZHP | Agreed | |
| Baozhen | Chen | Director | Assurance | ZHP | Agreed | |
| | | | Quality Assurance | | | |
| Dongqin | Wang | Assistant Director | at Chuannan Site East Zone | ZHP | Agreed | |
| | | - London Director | | | . 15.000 | |
| | | | Finished Dose | | | |
| | | | Quality Assurance | | | |
| Minli | Zhang | Director | and Quality Control | ZHP | Agreed | |
| | | | | | | |
| | | | Quality Control | | | |
| | | | (API Division- | | | |
| Qiangming | Li | Director | Chuannan Site) | ZHP | Agreed | |
| | | | API Quality | | | |
| Wenbin | Chen | Analysis Director | Research | ZHP | Agreed | |
| Wenquan | Zhu | Director | API Quality Research | ZHP | Agreed | |
| enquari | | 51100101 | | | | |
| | | | <u> </u> | | | |
| Vianhan- | Thac | Director | Quality Assurance (Chuannan Site) | ZHP | Dienstad | Part of core ZHP group identified as meeting attendees regarding the contamination in Duane Morris 6.21.19 correspondence to FDA (PRINSTON00073192) |
| Xiaohong | Zhao | Director | I/Ciiuaiiiaii Site) | Lein | Disputed | 1 DA (1 KING 1 O 1000 0 / 3 1 7 2) |

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|---------------------|-----------|-------------------------------|-----------------------------------------------------|------------|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hongliang | Wang | | Quality | ZHP | Disputed | Prepared Method Validation Report of Valsartan PRINSTON00031401 (According to published literature, "[f]or the pharmaceutical industry, method validation is crucial to ensure the product quality as regards both therapeutic efficacy and patient safety. The most critical step in validating a method is to establish a protocol containing well-defined procedures and criteria. A well planned and organized protocol, such as the one proposed in this paper, results in a rapid and concise method validation procedure for quantitative high performance liquid chromatography (HPLC) analysis." See https://conservancy.umn.edu/bistream/handle/11299/172043/cop_article_496630.pdf?sequence=1&isAllowed=y/ ; Checked significant tests for Valsartan impurities See, e.g., PRINSTON00023107; reviewed Method Validation Report of Valsartion for correctness and integrity PRINSTON00022665 |
| Cunxiao (Jenson) | Ye | Vice President | Quality Assurance, Headquarters | ZHP | Disputed | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158; Approved the Deviation Investigation Reports (root-cause analysis of the contamination) of Valsartan TEA Process PRINSTON0073443, etc. |
| Caifeng | Zhao | Manager | Quality Assurance | ZHP | Disputed | Principal Author of ZHP's 11.5.18 Deviation Investigation Report (root-cause analysis of the contamination) of Valsartan TEA Process V1, 2, & 3 PRINSTON0073443, 0075797, 0076100 |
| Y.F. | Chen | Senior Supervisor | API Quality Assurance | ZHP | Disputed | Reviewed Validation Report of Analytical Method for Azide in Valsartan for correctnesss and integrity PRINSTON00018712 (the removal of azide during the manufacturing process is suspected to contribute to the contamination); Reviewed and approved Validation Report of LC-MS Method for NDBA, another nitrosamine, in Losartan Potassium PRINSTON0074642; reviewed and approved the Validation Report of LC-MS Method for NMBA, another nitrosamine, in Irbesartan PRINSTON0074712 |
| Hu | Guangping | Director | Quality Control | ZHP | Disputed | QC Director regarding Valsartan tests related to sodium nitrite, which is suspected to contribute to the contamination PRINSTON00072721 |
| Huang | Rui | Director | Quality Control | ZHP | Disputed | Referenced in 35 separate documents in core document production, some regarding significant tests for impurities in Valsartan. See, e.g., PRINSTON00023107 |
| Xie | Chaojun | Analyst | Quality Control | ZHP | Disputed | QC Analyst who conducted tests regarding zinc chloride and DMF, both substances suspected of contributing to the contamination: PRINSTON00072692, 72743, and 00080383 |
| Qiang | Zhou | Analyst | Quality Research | ZHP | Disputed | Drafted Validation Report of GC-MS Method for Detection of NDMA in Valsartan Tablets and Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326, 36625 |
| Shang | Fei | QP | Quality VP | ZHP | Disputed | Reviewed and approved the third version of the Deviation Investigation (root-cause analysis) into the Valsartan TEA process PRINSTON0076100 |
| Tong | Wu | Analyst | API Quality Research | ZHP | Disputed | Drafted Validation Report of GC-MS Method for Detection of NDMA in Valsartan Tablets and Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326, 93 |
| Wenping | Hu | Team Leader | Quality Research | ZHP | Disputed | Reviewed Comparison of Valsartan USP Method and In-house Method for Integrity and Correctness PRINSTON00064389 (This document compares the impurities found in USP standard Valsartan with those found in ZHP's Valsartan); Reviewed data in Hydrochlorothiazide Residual Solvent Method Validation Report PRINSTON00064288 |
| Jieyun Zheng | Wang | Director Deputy Manager | Quality Assurance Quality Assurance | ZHP ZHP | Disputed P - 10.8.19 | According to the Valsartan DMF, "[s]he is responsible for QA/GMP auditing and the QC/GMP file management for all products" PRINSTON00077850; signed Valsartan GMP Certification PRINSTON00077832. On 12/4/19, ZHP said this person left ZHP in 2008, and ZHP does not have any of their emails. ZHP could not confirm whether ZHP had any other electronic or physical documents from this person. Executed numerous cGMP certifications, and many of Plaintiffs claims are based on violations of cGMPs re Valsartan. See, e.g. PRINSTON00038190 |
| Zhizhang | Ding | Assistant Manager | Formulation Quality Assurance | ZHP | P - 11.12.19 | Reviewed and approved Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384; Signed off on correction of the valsartan manufacturing process intended to prevent future contamination PRINSTON0000471 |
| Xiong | Fei | Analyst | Quality Control | ZHP | P - 10.8.19 | Analyst of Valsartan tests related to sodium nitrite, which is suspected to contribute to the contamination PRINSTON00080367; 71698; 72721 |
| Yinhua | Tang | Assistant Director/Manager | Quality Control (API Division- Chuannan Site) | ZHP | P - 11.12.19 | Reviewed and signed off on Deviation Investigation Reports (root-cause analysis of the contaminat) of Valsartan TEA Process PRINSTON0073443, etc.; attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| Yun | Jin | Supervisor | Chuannan Quality Control | ZHP | P - 11.12.19 | Drafted Assay Method Validation Report for Valsartan (Supplement) PRINSTON00009948 (An assay method validation is the process of determining whether the tests, or assays, are accurate and sufficient; it includes chromatograms); draft Chiral Purity Analytical Method Validation Protocol for TDCI Compound PRINSTON00077405 |
| Tian | Zhang | Analyst | Chuannan Quality Control | ZHP | P - 11.12.19 | Reviewed and signed off on Assay Method Validation Report for Valsartan (Supplement) PRINSTON00009948 (An assay method validation is the process of determining whether the tests, or assays, are accurate and sufficient; it includes chromatograms); reviewed and signed off on Chiral Purity Analytical Method Validation Protocal for TDCI Compound PRINSTON00077405 |
| Xianhua | Zhang | Deputy Director | Chuannan Quality Control | ZHP | P - 11.12.19 | Reviewed and signed off on Assay Method Validation Report for Valsartan (Supplement) PRINSTON00009948 (An assay method validation is the process of determining whether the tests, or assays, are accurate and sufficient; it includes chromatograms); reviewed and signed off on Chiral Purity Analytical Method Validation Protocal for TDCI Compound PRINSTON00077405 |
| Yuping | Chen | Deputy Manager | Formulation Quality Control | ZHP | P - 11.12.19 | Author of Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384 |
| Xiaoling | Li | Manager | Formulation Quality Control | ZHP | P - 11.12.19 | Reviewed and signed off on Elemental Impurity Risk Assessment Report for Valsartan Tablets PRINSTON00036384 |
| Tan | Xiao | Senior Supervisor | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation Report of GC-MS Method for Detection of NDMA in Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326; reviewed and approved Validation report of the LC-MS method for NDBA in Losartan Potassium PRINSTON0074642; reviewed and approved the Validation Report of LC-MS Method for NMBA in Irbesartan PRINSTON0074712 |

| | | 1 | | | | I |
|---------------------------|--------|---------------------------------------------------|-----------------------------------------------------------------|-----|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Nan | Tong | Senior Supervisor | API Quality Research | ZHP | P - 11.12.19 | Approved the cGMP compliance for its intended use of Report of GC-MS Method for Detection of NDMA in Valsartan and Hydrochlorothiazide Tablets PRINSTON00000326 |
| X. G., possibly Xingge | Liu | Quality Researcher | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation report of the LC-MS method for NDBA, a nitrosamine, in Losartan Potassium and Irbesartan PRINSTON0074177. ZHP has not told Plaintiffs that this person was not also involved in detecting nitrosamines in Valsartan. |
| Y.Y. possibly Yangyang | Не | Quality Researcher | API Quality Research | ZHP | P - 11.12.19 | Drafted Validation Report of LC-MS Method for NMBA, a nitrosamine, in Irbesartan and NMSA in Irbesartan PRINSTON0074712, 75156. ZHP has not told Plaintiffs that this person was not also involved in detecting nitrosamines in Valsartan. |
| Jian | Ye | Deputy Manager, Group I | Quality Control | ZHP | P - 11.22.19 | Put into effect the Method Validation, Report for Assay for Valsartan, which is the process of ensuring that the tests were accurate and adequate PRINSTON00070930 |
| | | General Detection, | | | | |
| Houming | Zhou | Technical Deputy Director | Study/Research Department | ZHP | P - 11.22.19 | ZHP's organization chart shows that this person had a signficant role in ensuring the quality of ZHP's API. ZHP has not provided any additional information regarding this person. |
| Xiao | Yu | Associate Director | API Quality Study/Research Department | ZHP | P - 11.22.19 | ZHP's organization chart shows that this person had a signficant role in ensuring the quality of ZHP's API. ZHP has not provided any additional information regarding this person. |
| Yang | Han | Supervisor | Quality Research | ZHP | P - 11.22.19 | ZHP's organization chart shows that this person had a signficant role in ensuring the quality of ZHP's API. ZHP has not provided any additional information regarding this person. |
| | | Supervisor | API QR | ZHP | P - 11.22.19 | Prepared Comparison of Valsartan USP Method and In-house Method PRINSTON00064389; put into effect the Method Validation for Valsartan PRINSTON00022665 |
| Chaohua | Bao | Supervisor | APTQK | ZHP | P - 11.22.19 | Audit consistency of document and cGMP compliance in many documents See, e.g., throughout PRINSTON00022331-23004; |
| Jianzhi | Zhao | | QA | ZHP | P - 12.2.19 | PRINSTON0010056. Many of Plaintiffs' claims are based on violations of cGMPs. |
| Meng | Zheng | Manager | QA | ZHP | P - 12.2.19 | Signed cGMP Certification for Valsartan PRINSTON00022284. Many of Plaintiffs' claims are based on violations of cGMPs. Manufacturing |
| Xiaoming | Liu | Head | Technical for Finished Dose Technical | ZHP | Agreed | Manufacturing |
| Peng | Dong | Deputy Director | Department | ZHP | Agreed | |
| | | | ZHP Facility Director API Manufacturing Chuannan Site, | | | |
| Peng | Wang | Senior Director | West Zone | ZHP | Agreed | |
| | | | Technical, API Chuannan site West Zone (counterpart to | | | |
| Wenling | Zhang | Director Assistant | Peng Dong) | ZHP | Agreed | |
| Wei | Chen | Deputy Director | Production Department | ZHP | Agreed | |
| Yongjun | Jin | Factor Assistant Director | Manufacturing | ZHP | Disputed | Identified in Valsartan DMF as a "professional engineer," and "has a wide experience at production technology management and is responsible for the technological development of all bulk drugs" PRINSTON00077836 |
| Youhu | Wang | Deputy Director of Production and Operation | | ZHP | Disputed | Identified in Valsartan DMF as "responsible for Valsartan" PRINSTON00077836; appears in the text of later documents, such as ZHP's Response to the FDA's August 2018 inspection PRINSTON0074892 |
| | | API and | | | | |
| Jiangzhong | Yu | Intermediate Plant Manager | Manufacturing | ZHP | Disputed | Identified in Valsartan DMF as responsible for all bulk drugs (including intermediates) at ZHP PRINSTON00077836 |
| | | | API Operations/Facility Director, API | | | |
| Lijin | Jiang | VP | Chuannan Site, East Zone | ZHP | Disputed | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| | | | Engineering and Maintenance, API Chuannan site East | | | |
| Zhengjun | Jia | Director | Engineering and Maintenance, API | ZHP | Disputed | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| Junhui | Zuo | Deputy Plant Director | Chuannan site West Zone | ZHP | Disputed | Attended close out meeting on 5.19.17 regarding FDA inspection PRINSTON0074158 |
| Chunmin | Xu | Vice President | | ZHP | Disputed | Identified as Valsartan personnel in DMF PRINSTON00070584, 79392. On 12/4/19, ZHP said this person left ZHP in 2015, and ZHP does not have any of their emails. ZHP could not confirm whether ZHP had any other electronic or physical documents from this person. |
| Ruqi | Yao | Factory Assistant Director | | ZHP | Disputed | Identified as Valsartan personnel in DMF PRINSTON00070587, 79392. On 12/4/19, ZHP said this person left ZHP in 2012, and ZHP does not have any of their emails. ZHP could not confirm whether ZHP had any other electronic or physical documents from this person. |
| Kai | Yang | Technical Manager | | ZHP | Disputed | Identified as Valsartan personnel in DMF PRINSTON00070587, 79392. On 12/4/19, ZHP said this person left ZHP in 2014, and ZHP does not have any of their emails. ZHP could not confirm whether ZHP had any other electronic or physical documents from this person. |
| | | ger | Chuannan Product | | | The head of ZHP's manufacturing department at the facility that manufactured Valsartan, presumably communicated between |
| Meng | Yanhua | General Manager | Technical Center | ZHP | Disputed | her subordinates, other departments, and senior management regarding Valsartan manufacturing. |

| | | | Formulation | | | Author of Elemental Impurity Risk Assessment Report for Valsartan Tablets and Valsartan and Hydrochlorothiazide Tablets |
|------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Lina | Wu | Senior Supervisor | Technology at ZHP | ZHP | P - 11.12.19 | PRINSTON00036384, 70161 |
| | | | | | | |
| Hu | Zhou | Factory Director | | ZHP | P - 11.22.19 | Identified as Valsartan personnel responsible for production and technology in DMF PRINSTON00070586 |
| | | 1 | | | | * |
| | | | | | | |
| | | | Chuannan Product | | | As the second in command at ZHP's Technical Department in the facility manufacturing Valsartan API, this person was |
| Yan | Fengfeng | Director of Tech | Technical Center | ZHP | P - 11.22.19 | responsible for developing the manufacturing process for Valsartan. |
| | | | | | | |
| | | | | | | |
| | Z | A ista Dissatas | Chuannan Product | ZUD | D 11 22 10 | The assistant to Dong Peng, who ZHP admits is a proper custodian. ZHP has not given Plaintiffs any additional information |
| Liang | Zunjun | Associate Director | Technical Center | ZHP | P - 11.22.19 | regarding this person. |
| | | | | | | |
| | | | | | | |
| Hu | Zhichen | Manager | Chuannan Product Technical Center | ZHP | P - 11.22.19 | Manager in the department that developed the manufacturing process for Valsartan. ZHP has not given Plaintiffs any additional information regarding this person. |
| 11u | Zinchen | ivianagei | recinical center | ZIII | 1 - 11.22.19 | information regarding this person. |
| | | | | | | |
| | | | | | | |
| | | | Chuannan Product | | | This person's title is Valsartan. They are in the department that developed the manufacturing process for Valsartan. ZHP has not |
| Zhan | Xiaohui | "(Valsartan)" | Technical Center | ZHP | P - 11.22.19 | given Plaintiffs any additional information regarding this person. |
| Lihong | T | T | Regulatory Affairs | I | T T | Regulatory |
| (Linda) | Lin | Director | Department | ZHP | Agreed | |
| Yanfeng | | Deputy Director / | | | | |
| (Lucy) | Liu | Manager | Regulatory Affairs | ZHP | Agreed | |
| Ying Ting (Ada) | Xiong Zhou | Supervisor Assistant Director | Regulatory Affairs Regulatory Affairs | ZHP ZHP | Agreed Agreed | |
| Tilig (Ada) | Znou | Assistant Director | | ZIII | Agreed | |
| т. | T : | Dto Mouse on | API Patent, Regulation Affairs | ZUD | Discorted | Head of patents at ZHP, which has patents regarding Valsartan, one of which is for the manufacturing process that led to the contamination. |
| Jie | Lin | Deputy Manager | | ZHP | Disputed | |
| Sun | Dengxue | Manager | API R&D, Regulation Affairs | ZHP | P - 11.22.19 | Manager of API Research and Development in the Regulatory Department that handled Valsartan. ZHP has not given Plaintiffs any additional information regarding this person. |
| Dui | Dengade | | regulation / trians | 12711 | 111.22.17 | Procurement |
| Min | Hu | | Purchasing | ZHP | Agreed | |
| Weiwei Min | Xu Xu | | Purchasing | ZHP ZHP | Agreed | |
| Zheng | Gaozhe | | Purchasing Purchasing | ZHP | Agreed Agreed | |
| - 0 | _ | | | | | |
| | | | | | | API Sales |
| Minda | Cai | Former VP | ADI Sales | ZHP | Agreed | API Sales |
| Minda | Cai | Former VP | API Sales | ZHP | Agreed | API Sales |
| | | | Business | | | API Sales |
| Minda | Cai | Former VP | Business Development | ZHP | Agreed Agreed | API Sales |
| Jie | Wang | | Business Development Business | | Agreed | API Sales |
| Jie Sheng | Wang Zhong | VP Director | Business Development Business Development Business | ZHP | Agreed Agreed | API Sales |
| Jie | Wang | VP | Business Development Business Development Business Development | ZHP | Agreed | API Sales |
| Jie Sheng | Wang Zhong | VP Director | Business Development Business Development Business Development Business | ZHP | Agreed Agreed | API Sales |
| Jie Sheng | Wang Zhong | VP Director | Business Development Business Development Business Development | ZHP | Agreed Agreed | API Sales |
| Jie Sheng Hongchao | Wang Zhong Li | VP Director | Business Development Business Development Business Development Business Development Business | ZHP ZHP | Agreed Agreed | API Sales |
| Jie Sheng Hongchao | Wang Zhong Li Xu | VP Director Manager | Business Development Business Development Business Development Business Development Business Development, API Sales | ZHP ZHP ZHP | Agreed Agreed Agreed Agreed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how |
| Jie Sheng Hongchao | Wang Zhong Li | VP Director | Business Development Business Development Business Development Business Development Business | ZHP ZHP | Agreed Agreed | |
| Jie Sheng Hongchao | Wang Zhong Li Xu | VP Director Manager | Business Development Business Development Business Development Business Development Business Development, API Sales | ZHP ZHP ZHP | Agreed Agreed Agreed Agreed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how |
| Jie Sheng Hongchao | Wang Zhong Li Xu | VP Director Manager | Business Development Business Development Business Development Business Development Business Development, API Sales | ZHP ZHP ZHP | Agreed Agreed Agreed Agreed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. |
| Jie Sheng Hongchao Mi Yihua | Wang Zhong Li Xu Wang | VP Director Manager Vice President Manager Assistant, | Business Development Business Development Business Development Business Development Business Development Sales Sales | ZHP ZHP ZHP ZHP ZHP | Agreed Agreed Agreed Disputed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and |
| Jie Sheng Hongchao | Wang Zhong Li Xu | VP Director Manager Vice President | Business Development Business Development Business Development Business Development Business Development Sales Sales | ZHP ZHP ZHP | Agreed Agreed Agreed Agreed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. |
| Jie Sheng Hongchao Mi Yihua | Wang Zhong Li Xu Wang | VP Director Manager Vice President Manager Assistant, | Business Development Business Development Business Development Business Development Business Development Sales Sales | ZHP ZHP ZHP ZHP ZHP | Agreed Agreed Agreed Disputed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and |
| Jie Sheng Hongchao Mi Yihua | Wang Zhong Li Xu Wang | VP Director Manager Vice President Manager Assistant, Business Group I | Business Development Business Development Business Development Business Development Business Development Sales Sales | ZHP ZHP ZHP ZHP ZHP | Agreed Agreed Agreed Disputed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and Lina Wang did not both work on Valsartan. |
| Jie Sheng Hongchao Mi Yihua Fengyang | Wang Zhong Li Xu Wang | VP Director Manager Vice President Manager Assistant, Business Group 1 Manager Assistant, | Business Development Business Development Business Development Business Development Business Development, API Sales Sales | ZHP ZHP ZHP ZHP ZHP | Agreed Agreed Agreed Disputed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and Lina Wang did not both work on Valsartan. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and |
| Jie Sheng Hongchao Mi Yihua | Wang Zhong Li Xu Wang | VP Director Manager Vice President Manager Assistant, Business Group I | Business Development Business Development Business Development Business Development Business Development Sales Sales | ZHP ZHP ZHP ZHP ZHP | Agreed Agreed Agreed Disputed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and Lina Wang did not both work on Valsartan. |
| Jie Sheng Hongchao Mi Yihua Fengyang Lina | Wang Zhong Li Xu Wang Tang | VP Director Manager Vice President Manager Assistant, Business Group I Manager Assistant, Business Group II Outcome Service | Business Development Business Development Business Development Business Development, API Sales Sales Sales | ZHP ZHP ZHP ZHP ZHP ZHP | Agreed Agreed Agreed Disputed Disputed Disputed | Co-head of ZHP's Sales Department, which handled Valsartan. ZHP has said that she is a recent hire, but has not said how recent. ZHP also admits that she has knowledge of the Valsartan recall. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and Lina Wang did not both work on Valsartan. Manager in the Sales Department who handled Key Accounts for Valsartan. ZHP has not told Plaintiffs that Fengyang Tang and Lina Wang did not both work on Valsartan. As the Director of Customer Service, this person very likely dealt with customer complaints regarding Valsartan. ZHP has not |
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| Hai | Wang | President since 2005 | | Vice President at Huahai US since 2005 (Linkedin), Sr. Vice President at Prinston (Linkedin), & President at Solco (Prinston's website) | Agreed | |
|-------------------|--------|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| John | Iozzia | Director | Sales | Huahai US | Agreed | |
| | | | | | | |
| Zhi | Chen | | | Huahai US | Disputed | Listed as contact for ZHP's US Agent to the FDA for Valsartan, Huahai US PRINSTON00072295 Author of Cover Letter re: Valsartan ANDA PRINSTON00066953-54; Listed as contact for the US Agent, Huahai US, for |
| Qun (Kathy) | Zhang | Senior Manager | Regulatory Affairs | Huahai US | Disputed | Valsartan PRINSTON00073120; Same PRINSTON00072212 |
| Min (Michelle) | Hu | Manager of Business Development and Senior Director of Business Development | | Huahai US (2007-2012) and Prinston (2012- Present), respectively | Disputed | Given her title and Huahai US's and Prinston's significant role in bringing ZHP's Valsartan to the United States, Plaintiffs believe that she has important, relevant, and probative documents in this case. The ZHP defendants do not dispute this. They simply say that other custodians "have superior information related to Valsartan." |
| Yiming | Tang | | | | P - 11.22.19 | Contact Person for ZHP's U.S. Agent to FDA for Valsartan PRINSTON0076915 and many other documents regarding Huahai US as ZHP's U.S. agent to the FDA for Valsartan PRINSTON00010626, PRINSTON00008984, PRINSTON00078888, etc. |
| | l | <u> </u> | <u> </u> | <u> </u> | <u> </u> | Prinston |
| Xiaodi | Guo | Executive Vice President and Chief Scientific Officer for Prinston & Huahai US | | Huahai US (linkedin), Prinston (website), and Solco (affidavits of service) | Agreed | |
| Hai | Wang | | | Vice President at Huahai US since 2005 (Linkedin), Sr. Vice President at Prinston (Linkedin), & President at Solco (Prinston's website) | Agreed | |
| Chris | Keith | Senior Vice President / VP | Salac | Solco/Prinston at some point as VP | Agreed | |
| Chris | Keitii | 1 1 CSIUCIII / V P | Sales | v f | Agreed | |
| Remonda | Gergis | VP | Quality Assurance | Prinston | Agreed | |
| | | | Head of Regulatory | | | |
| Lijie Minfa | Wang | VP VP | Analytical Operations and Quality Control | Prinston Prinston | Agreed | She is a senior officer of Prinston, in charge of Analytical Operations and Quality Control. Identified as a planned attendee in Prinston's 6.18.18 Email Meeting Request to FDA initially advising the FDA of Valsartan's contamination (PRINSTON00000050). |
| | | | , , | | | |
| Wei (Helena) | Tong | Director | Regulatory Affairs | Prinston | Disputed | Listed on ANDA Documents, Signed ANDA, and routinely corresponded with the FDA. For example, PRINSTON00037372, PRINSTON00054685, , PRINSTON00031790. Her full name appears in 106 documents from Core Discovery. |
| Guangyu | Luo | Associate (2013- 2015), Senior Associate (2015- 2016), Specialist (2016-2017), Manager (2017- Present) | | Prinston | Disputed | Signed ANDA for Valsartan PRINSTON00066560, PRINSTON00033715, PRINSTON00034648, PRINSTON00066787, PRINSTON00066707, PRINSTON00066848; "Regulatory Affairs, mainly on regulatory submissions (from draft to e-CTD compilation), pharmacovigilance (AE handling and submission) and generic labeling (content, artwork and SPL)." -Linkedin |
| Lesley | Zhu | SVP, Business Development & Portfolio | Sales | Prinston | Disputed | Received email from Frederick Ball re: FDA correspondence along with Jun Du; Same PRINSTON0073198; Cc'd on letter to FDA with Jun Du PRINSTON00079000; Sent letter to FDA re: authorizing the FDA to share information with the EMA PRINSTON0007470-71; PRINSTON0073192-96; Cc'd on letter to FDA with Jun Du PRINSTON00079001-02 |
| | • | • | • | | | · |

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| Min (Michelle) | Hu | Manager of Business Development and Senior Director of Business Development | | Huahai US (2007-2012) and Prinston (2012- Present), respectively | Disputed | Given her title and Huahai US's and Prinston's significant role in bringing ZHP's Valsartan to the United States, Plaintiffs believe that she has important, relevant, and probative documents in this case. The ZHP defendants do not dispute this. They simply say that other custodians "have superior information related to Valsartan." |
|-------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Peng | Shang | Senior Associate of Business Development/Supp ly Chain (2016- Present) | | Prinston | Disputed | Given this person's title and Prinston's significant role in bringing ZHP's Valsartan to the United States, Plaintiffs believe that she has important, relevant, and probative documents in this case. The ZHP defendants do not dispute this. They simply say that other custodians "have superior information related to Valsartan." |
| Ning | Zhang | Specialist | Regulatory Affairs | Prinston | P - 12.2.19 | Regulatory Affairs Approval for Corrected Valsartan Manufacturing Process PRINSTON00000479 |
| | | | | | | Solco |
| Xiaodi | Guo | Executive Vice President and Chief Scientific Officer for Prinston & Huahai US | | Huahai US (linkedin), Prinston (website), and Solco (affidavits of service) | Agreed | |
| | | | | Vice President at Huahai US since 2005 (Linkedin), Sr. Vice President at Prinston (Linkedin), & President at Solco (Prinston's | | |
| Hai | Wang | | | website) | Agreed | |
| Chris | Keith | Senior Vice President / VP | Sales | Solco/Prinston at some point as VP | Agreed | |
| | | Vice President (2018-Present); Executive Director, Sales (2016-2018); Senior Director of National Accounts (2014-2016); Director of National Accounts (2012-2013); National Account Manager (2010- | | | | |
| David | Ayres | 2012) National Account | Sales | Solco | Agreed | Author of Only Solco-stamped document, a list of Valsartan customers. He must have have many other documents regarding |
| Matthew | Arnold | Manager from | | Solco | Disputed | these customers. Solco has not said otherwise. |
| | | | | | Shangha | i Syncores Technologies, Inc. |
| Eric | Gu | Manager | | Shanghai Syncores | P - 10.8.19 Pr | On list of planned attendees for meeting with FDA re: the contamination PRINSTON0073192-96. Syncores developed the manufacturing process for the contaminated Valsartsan, and his inclusion on this list establishes that he has signficant knowledge about Syncores' involvement in the contamination. inbury BioPharm Ltd. |
| Dachuan | Zhao | Executive Deputy General Manager of Prinbury | | Prinbury | P - 11.12.19 | Attended close out meeting on 5.19.17 regarding FDA inspection, identified as Vice President of Analytical Shanghai R&D Center PRINSTON0074158; "Dr. Zhao has comprehensive and in-depth understanding and rich experience in key areas such as product development (QbD), analysis, product declaration, quality control, quality assurance, FDA regulations, and FDA audits." -Prinbury website (via Google Translate). Identified in core discovery as Vice President. Analytical, Shanghai R&D Center PRINSTON0076915. Prinbury developed the finished dose manufacturing process for Valsartan, including many of the tests conducted during that process, as shown below. |

| | 1 | 1 | 1 | 1 | | |
|------------|-------|----------------------------|-----------------------|----------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Li or Lily | Tan | Director Deputy General | Project Management | Prinbury | P - 11.12.19 | Worked on numerous important Valsartan documents, many of which involed chromatography, which can detect nitrosamines: Reviewed and Signed Off on Method Robustness Study Report re: Content Uniformity Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039541; Reviewed and Signed Off on Method Validation Report on Identification, Assay and Content Uniformity Determination of Valsartan PRINSTON00029805; Approved Method Verification Report for Valsartan PRINSTON00029309; Approved Method Validation Report re: Dissolution Test of Valsartan and Hydrochlorothiazide PRINSTON 00039663; Approved Method Verification and Assay Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039493; Approved Method Verification and Assay Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039495; Approved Method Verification Report re: Crapical Impurities Determination Valsartan and Hyrdochlorothiazide PRINSTON00039499; Approved Submission Batch Stability Study Report for Valsartan and Hyrdochlorothiazide PRINSTON0003499; Approved Submission Batch Stability Study Report re: Dissolution Determination of Valsartan and Hyrdochlorothiazide PRINSTON0003499; Approved Submission Batch Stability Study Report re: Dissolution Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039645; Approved Method Verification Report re: Dissolution Test of Valsartan and Hyrdochlorothiazide PRINSTON00039605; "12 years of experience in drug development, analysis, quality management and project management. Good at the establishment and management of quality system and project management and project management and management and project management. Good at the establishment and management of quality system and project management. Project management. Good at the establishment and management of Primbury website (via Google Translate). |
| | | Manager of Analysis and | | | | This person was previously on the Prinbury website, but no longer is. Wei Tian's title and Prinbury's work on Valsartan establish that Wei Tian is likely to have worked on Valsartan related issues and potentially had involvement in and/or is knowledgeable as |
| Wei | Tian | Research | | Prinbury | P - 11.12.19 | to how it was tested, among other things. |
| | | | | | | Worked on numerous important Valsartan documents, many of which involed chromatography, which can detect nitrosamines: Prepared Method Verification Report re: Identification and Assay Determination of Valsartan and Hyrdochlorothiazide PRINSTON0039439; Prepared Method Verification Report re: Organic Impurities Determination for Valsartan and Hyrdochlorothiazide PRINSTON00039715; Prepared Submission Batch Stability Study Report re: Masartan and Hyrdochlorothiazide PRINSTON00039499; Prepared Wethod Valsartan and Hyrdochlorothiazide PRINSTON00039499; Prepared Method Validation Report re: Content Uniformity Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039409; Prepared Method Valsatidation Report re: Content Uniformity Determination of Valsartan and Hyrdochlorothiazide PRINSTON0003960; Prepared Dissolution Comparison Study Report re: Valsartan PRINSTON00029309; Prepared USP Method Equivalence Study Report re: Dissolution Test of Valsartan and Hyrdochlorothiazide PRINSTON00039603; Prepared Method Robustness Study Report re: Dissolution Determination for Valsartan and Hyrdochlorothiazide PRINSTON00039645 |
| Shine | Chen | Scientist | | Prinbury | P - 11.12.19 | |
| Tina | Liu | Senior Scientist | | Prinbury | P - 11.12.19 | Worked on numerous important Valsartan documents, many of which involed chromatography, which can detect nitrosamines: Reviewed and Signed Off on Method Verification Report re: Identification and Assay Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039439; Reviewed Method Verification Report re: Organic Impurities Determination for Valsartan and Hyrdochlorothiazide PRINSTON00039715; Prepared USP Method Equivalence Study Report re: Assay Determination of Valsartan PRINSTON00020861; Reviewed and Signed Off on Method Validation Report re: Dissolution Test of Valsartan and Hyrdochlorothiazide PRINSTON00039663; Prepared Method Validation Report re: Organic Impurities Determination for Valsartan PRINSTON0002905; Reviewed and Signed Off on Dissolution Comparision Study Report for Valsartan and Hyrdochlorothiazide PRINSTON00059114; Reviewed and Signed Off on Submission Batch Stability Study Report re: Valsartan and Hyrdochlorothiazide PRINSTON00064193; Reviewed and Signed Off on USP Method Equivalence Study Report re: Content Uniformity Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039499; Reviewed and Signed Off on Method Verification Report re: Dissolution Test of Valsartan and Hyrdochlorothiazide PRINSTON00039499; Reviewed and Signed Off on Method Verification Report re: Dissolution Test of Valsartan and Hyrdochlorothiazide PRINSTON00039800 |
| Yun | Tian | Senior Director | | Prinbury | P - 11.12.19 | Approved Method Validation Report on Identification, Assay and Content Uniformity Determination of Valsartan PRINSTON00020805; Approved Method Verification Report re: Identification and Assay Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039439; Approved Method Robustness Study Report re: Content Uniformity Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039541; Approved Method Verification Report re: Organic Impurities Determination of Valsartan and Hyrdochlorothiazide PRINSTON00039715; Approved Dissolution Comparison Study re: Valsartan and Hyrdochlorothiazide PRINSTON00039090; Approved Comparison Study Report re: Valsartan and Hyrdochlorothiazide PRINSTON00039663; Approved USP Method Equivalence Study Report re: Dissolution Test of Valsartan and Hyrdochlorothiazide PRINSTON00039603; Approved USP Method Equivalence Study Report re: Orlasartan and Hyrdochlorothiazide PRINSTON00039603; Approved USP Method Equivalence Study Report re: Content Uniformity Determination of Valsartan and Hyrdochlorothiazide PRINSTON000399560; Approved Submission Batch Stability Study Report re: Content Uniformity Determination of Valsartan PRINSTON000395560; Approved Submission Batch Stability Study Report for Valsartan and Hyrdochlorothiazide PRINSTON000395560; Approved Method Validation Report re: Dissolution Determination for Valsartan and Hyrdochlorothiazide PRINSTON00039645; Approved Method Verification Report re: Dissolution Test of Valsartan and Hyrdochlorothiazide PRINSTON00039800; She "is responsible for the development and validation of analytical methods for pharmaceutical products. 11 years of experience in the analysis, development and quality control of APIs and pharmaceutical preparations. He is good at quality research and control in the drug development process of IND and NDA, including the relevant stability tests. Rich cGMP analysis laboratory team construction and management experience, familiar with FDA / EMEA cGMP regulations, and participated in multiple FDA, EMEA cGMP redultis." -P |
| 1 un | Tiali | Schol Director | | rinioury | F - 11.12.19 | weosie (via Googie Haissate) |
| Alex | Liu | Scientist | | Prinbury | P - 11.12.19 | Worked extensively on USP Method Equivalence Study Report on Assay Determination using Chromatography, which can detect nitrosamines, of Valsartan PRINSTON00020861; Prepared Dissolution Comparison Study Report of Valsartan PRINSTON00050114; |
| Ashley | Lin | Associate Scientist | | Prinbury | P - 11.12.19 | Prepared Method Robustness Study Report for Content Uniformity Determination, using Chromatography, which can detect nitrosamines, of Valsartan PRINSTON00039541; Prepared USP Method Equivalence Study Report, using Chromatography, which can detect nitrosamines, re: Dissolution Test of Valartan PRINSTON00021157; Prepared Method Validation Report for Dissolution Test, using Chromatography, which can detect nitrosamines, of Valsartan and Hydrochlorothiazide PRINSTON00039663 |

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| Yulu (Luke) | Wang | Executive Director | Prinbury | Reviewed and approved many Master Production Batch Record Approval See, e.g., PRINSTON00064070, PRINSTON00063906, PRINSTON00063742, PRINSTON00038525. Batch Records contain actual data and step by step process for manufacturing each batch. Batch manufacturing record is like a proof that batches were properly made and checked by quality control personnel. See https://process-xe.sarjen.com/batch-manufacturing-records-important-according-gmp/. |
|-------------|------|--------------------|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Angela | An | Scientist | Prinbury | Prepared Method Validation Report on Identification, Assay and Content Uniformity Determination of Valsartan, using Chromatography, which can detect nitrosamines PRINSTON00020805 |